REMARKS

Claims 1, 3-14 and 16-18 currently are pending and have been examined. The objection to the inventors' declaration has been withdrawn.

Claims 1, 3-6, 10-14 and 16-18 are rejected as indefinite. Applicant has amended claim 16 to change the dependency and amended claim 1 to recite that the claimed synthetic and recombinant TA1 have bioactivity substantially similar to that of naturally occurring TA1 as disclosed in the specification at paragraph 13 and mentioned in the Office Action. A person of skill would know what is meant by this terminology, therefore this language is definite. See M.P.E.P. § 2175.05(b)(D). Applicant also refers the Office to further discussion below on this issue.

Claims 1, 3-6, 10-14 and 16-18 are rejected as assertedly failing to comply with the written description requirement. The Office states that the claims contain subject matter not described in the specification. The specific subject matter allegedly not described is not specifically indicated, however the Office provides a lengthy discussion concerning genera of biomolecules accompanied by mention of language in claim 1 reciting "synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1." Therefore Applicant assumes that this quoted language is what the Office considers to be lacking written description support. If this is not the case, Applicant requests clarification.

Applicant has amended claim 1 to incorporate language from the specification as mentioned by the Office and therefore submits that the claim as amended is fully supported by description in the original specification. The incorporated language refers to specific TA1 peptides in terms of both structure and function. Applicant submits that this language clearly defines the metes and bounds of the claimed subject matter and

that the claimed peptides have word-for-word support in the written description of the original specification.

Therefore, a skilled person would be able to immediately discern what peptides fall within claim 1 and would recognize immediately that the inventors had possession of these claimed peptides. All persons of skill are aware of the function and activity of TA1 and would immediately understand both the terminology and the TA1 peptides that were intended to be claimed by the inventors here and that these peptides were described by and possessed by the inventors. This is particularly true in light of the knowledge in the art concerning TA1 peptides. See specification, paragraph 26.

Applicant submits that the functional characteristics of TA1 peptides are correlated here to a structure or partial structure and that this combination of identifying characteristics distinguish the claimed invention from other materials. Therefore, one of skill would conclude that Applicant was in possession of the claimed species. Considering the structural and functional limitations of the claim together, the variability of the claimed peptides is greatly overstated by the Office. Methods of determining bioactivity of TA1 exist in the art. One of skill would quickly conclude that the inventors here had possession of peptides having the particular claimed structures based on native TA1 (i.e. substituted, deleted, elongated or replaced amino acids) and the bioactivity already attributed to naturally occurring TA1.

For the reasons discussed above, Applicant requests withdrawal of the rejection based on lack of written description.

Claims 1, 3-14 and 16-18 are rejected for assertedly lacking enabling support. The specific language in the claims to which the Office is referring is not clear, however the nature of the lengthy discussion appears to relate to the Office's doubt that the claimed method would or could be successful at totally preventing all cases of SARS in all persons. The Office is interpreting the word "prevent" in the claims to have an "absolute definition." This definition is used in spite of the Office's explicit admission that it is "notoriously well-accepted in the medical art that the vast majority of

affliction/disorders suffered by mankind cannot be totally prevented..." The Office is bound to interpret terms in accordance with accepted meaning in the art. The art recognizes that absolute and total prevention is not a reasonable goal (even for vaccines, as the Office asserts) and therefore this is not a reasonable interpretation or an interpretation that would be made by any skilled person in the medical arts when reading this claim. Even according to the Office's own understanding of the art, this is not a reasonable interpretation. Therefore, Applicant again objects to this interpretation of the term "prevent." It is not proper for the Office to choose an admittedly unreasonable interpretation of a word and then reject claims because its interpretation is unreasonable.

Applicant submits that the immune-stimulating bioactivity of TA1, as known in the art, has been found by the inventors here to be useful in both treating SARS and preventing its spread. The Office criticizes the present invention because the prior state of the art has not provided a treatment or preventative protocol for SARS and seems to take prior failure of others to be evidence that the present Applicant also has failed. This is not a proper or reasonable argument. All inventions have a legacy of prior art which previously failed to achieve them.

The Office, furthermore, has no reasonable basis for asserting that TA1 peptides having an art-recognized bioactivity do not successfully treat coronavirus respiratory infections. Experimentation to determine *in vivo* activity of any particular TA1 peptide, asserted to be undue by the Office, is a completely unreasonable standard as well. TA1 peptides that have art-recognized bioactivity substantially similar to TA1 need not be tested *in vivo* in SARS patient studies for the person of skill to recognize there utility. A simple test known in the art for *in vivo* determination of those peptides not already known to possess TA1 bioactivity would not be considered undue by a person of skill in the art. Thus, any testing which could be required under any conceivable standard would not be undue experimentation.

The Office considers the art to be unpredictable. This single factor in the analysis of enablement has extremely little impact. Applicant recognizes that in general the medical arts can be unpredictable, however when an Applicant has discovered a method, described it and disclosed it as effective, the past failure of others or difficulty in achieving the invention militates in favor of its patentability. Moreover, Applicant is not required to address the asserted unpredictability in the art as the Office seems to imply at page 14. The mere disclosure of the invention that solves the problem in the prior art is sufficient to address the problem.

Although it is the Office's burden to present facts which prove its assertions of lack of enablement, the Office here seems to be requiring that Applicant provide proof that the Office's conclusions are untrue. In particular, the main contention of the Office appears to be that it would be undue experimentation to determine whether the claimed peptides could be used for the claimed methods. Applicant has stated that TA1 peptides having the structural relationship and the functional relationship to TA1 as claimed are effective in the method. Applicant submits that this is a sufficient enabling disclosure.

In terms of enablement, Applicant has disclosed the bioactivity which is useful, the sequences that possess this activity as known in the art, the structure of the claimed peptides, the function of the claimed peptides, methods to obtain the peptides and to conjugate them with polymers, methods of administering the peptides, the dosages which are suitable and patient populations for the methods' use. Applicant submits that a skilled person would be able to practice the invention in its full scope.

For the reasons discussed above, Applicant requests withdrawal of the rejection for lack of enablement.

Claims 1, 3-12 and 16-17 are rejected as anticipated by Sherman et al., Hepatology 27: 1128-1135, 1998 (hereinafter "Sherman"). This reference is cited for teaching administration of TA1 "to patients." The Office asserts that these "patients" meet the claim limitations because any patient who does not have a coronavirus

infection meets the claim limitation. Applicant has amended claim 1 to incorporate language found in the original specification at paragraphs 11-12. The claim now specifies that the patient in the claimed method has a respiratory coronavirus infection, has had contact with a SARS carrier or is an asymptomatic SARS carrier.

The Sherman reference, published before SARS existed, did not disclose or suggest SARS carriers expressly or inherently. Furthermore, there is nothing in Sherman to indicate that any of the patients had a coronavirus respiratory infection. Applicant submits that Sherman does not anticipate the methods of the present invention and requests withdrawal of this rejection.

The Office has rejected claims 1, 3-9, 13 and 16-18 (provisionally) over claims 1-19 of serial no. 10/535,835 (hereinafter '835). These cited claims recite a method of treatment for protecting cells of a subject against radiation damage. The claims do not recite, mention, or even hint at a method for treating coronavirus infection, however the Office considers the completely distinct method of protection from radiation damage because it assertedly is possible for the method to be used in the same patients. The cited claim itself, which is the only disclosure available in making out a case of double patenting, does not recite the method claimed here and would not suggest to a skilled reader or guide a skilled reader toward any method for treatment or prevention or coronavirus. There is absolutely nothing in the cited claim (absent the hindsight provided by the Office from interpreting the language of the recited claim) that directs one to treat or prevent coronavirus. Nor would practice of either of the claimed inventions extend the patent rights of the other beyond its patent term.

The Office appears here to have confused the concept of double patenting and domination. The Office considers the '835 claims to encompass (dominate) the methods claimed here and therefore rejects on grounds of double patenting. Ignoring for the moment the propriety of the Office's initial conclusion of domination, this reasoning cannot support a double patenting rejection. See M.P.E.P. § 804(II). Nothing about treatment of cellular radiation damage would lead a reader toward

coronavirus infection treatment or prevention. Therefore, the claimed method is nonobvious over and patentably distinct from the cited claims.

For the reasons discussed above, the rejection made on grounds of double patenting is unsupported by the facts of this case and must be withdrawn.

Applicant requests reconsideration of the applicant and allowance of all pending claims at this time.

The response is timely. The Office is authorized to charge any fees deemed necessary in connection with this response to Deposit Account 02-2135.

Respectfully submitted,

By: _____

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